AMENDMENTS TO THE CLAIMS

Docket No.: 37998-237530

- 1. (Currently Amended) A process for purifying <u>alpha-1-antitrypsin (A1AT)</u> from <u>alpha-1-antitrypsin-A1AT-containing</u> solutions or from other protein components, comprising the <u>following steps:</u>
 - (a) subjecting an <u>alpha-1-antitrypsinA1AT</u>-containing solution to ion-exchange chromatography;
 - (b) adding detergents and optionally a solvent for inactivating lipid-enveloped viruses;
 - (c) followed by increasing the salt concentration to salt out the detergents.
- 2. (Currently Amended) The process according to claim 1, wherein said <u>alpha-1-antitrypsinA1AT</u>-containing solution has been obtained from <u>the group consisting of blood</u> plasma or its fractions, <u>preferably from</u> a reconstituted plasma fraction IV1 (Cohn), or is derived from a recombinantly or transgenically expressed <u>A1AT alpha-1-antitrypsin</u> preparation [[or]] <u>and</u> a fermentation supernantant.
- 3. (Currently Amended) The process according to claim 1, wherein ion-exchange chromatography is performed on an anion-exchange gel[[,]] preferably DEAE-Sepharose® or DEAE-Sepharose® Fast Flow.
- 4. (Currently Amended) The process according to claim 1, wherein said virus inactivation according to step (b) is effected with Triton X-100, Polysorbate 80 (Tween 80), TnBP tri-n-butyl phosphate and/or caprylic acid or caprylate, preferably at final concentrations of ≥

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0.1% (w/w) Triton and Tween 80, \geq 0.03% (w/w) TnBP tri-n-butyl phosphate, \geq 0.1 mM caprylic acid or caprylate, with an incubation time of \geq 0.1 hours[[,]] preferably \geq 1 hour, at \geq 4 °C, especially at \geq 15 °C.

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- 5. (Currently Amended) The process according to claim 1, wherein the salt concentration of the solution is brought to ≥ 0.5 M in step (c) and particles formed thereby are preferably removed by filtration.
- 6. (Currently Amended) The process according to claim 1, wherein <u>a further chromatography</u> on hydrophobic chromatographic materials is performed.
- 7. (Currently Amended) The process according to claim 1, wherein a treatment of the <u>alpha-1-antitrypsinA1AT</u>-containing <u>fraction solution</u> with a material <u>which contains comprising</u> heparin in an immobilized form (<u>heparin gel</u>) is performed.
- 8. (Currently Amended) The process according to claim 5, wherein a further virus inactivation step is performed afterwards, the virus inactivation step comprising preferably pasteurization in the presence of ≥ 0.5 M sodium citrate, amino acids, sugars or mixtures thereof.
- 9. (Currently Amended) The process according to claim 1, wherein the ion strength of the solution is preferably reduced by ultra-/diafiltration ultrafiltration, diafilarration, or ultrafiltration and diafiltration.

- 10. (Currently Amended) The process according to claim 1, wherein a separation of virus particles is performed[[,]] preferably by nanofiltration, preferably with filters having pore sizes of 15-20 nm.
- 11. (Currently Amended) The process according to claim 1, wherein the A1AT alpha-1antitrypsin solution fraction obtained is stored as a liquid, frozen or freeze-dried preparation.
- 12. (Currently Amended) A1AT Alpha-1-antitrypsin having a purity of > 90%, an activity of ≥ 0.8 PEU/mg in its active form, an IgA content of ≤ 1 mg/ml, a residual detergent content of < 50 ppm, especially < 10 ppm, and a monomer content of > 90%, based on the total amount of A1AT alpha-1-antitrypsin, wherein the active form of alpha-1-antitrypsin has a maximum activity of 100%.
- 13. (Currently Amended) The A1AT <u>alpha-1-antitrypsin</u> according to claim 12, obtainable by a process comprising the following steps:
 - (a) reconstitution of plasma fraction IV1 (Cohn) providing an alpha-1-antitrypsin solution;
 - (b) anion-exchange chromatography on DEAE-Sepharose® Fast Flow;
 - (c) optionally chromatography on a solid phase which comprises heparin in an immobilized form (heparin affinity chromatography);
 - (d) optionally hydrophobic interaction chromatography (HIC);

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virus inactivation with $\geq 0.1\%$ (w/w) Triton[[/]] and $\geq 0.03\%$ (w/w) TnBP tri-n-butyl (e) phosphate with an incubation time of ≥ 1 hour at ≥ 15 °C;

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- (f) addition of salt to increase the ion strength of the said solution; and
- removal by filtration of particles formed thereby. (g)
- 14. (Currently Amended) The A1AT alpha-1-antitrypsin according to claim 13, wherein a further virus inactivation step is performed afterwards, preferably the further virus <u>inactivation</u> step comprising pasteurization in the presence of ≥ 0.5 M sodium citrate, amino acids, sugars or mixtures thereof.
- 15. (Currently Amended) The A1AT alpha-1-antitrypsin according to claim 13, wherein the ion strength of the solution is preferably-reduced by ultra-/diafiltration ultrafiltration, diafiltration, or both ultrafiltration and diafiltration.
- 16. (Currently Amended) The A1AT alpha-1-antitrypsin according to claim 13, wherein comprising a virus inactivation and/or or a prion depletion or inactivation step is comprised, preferably comprising a separation of virus particles by nanofiltration, preferably with filters having pore sizes of 15-20 nm.
- (Currently Amended) The A1AT alpha-1-antitrypsin according to claim 13, wherein the 17. A1AT alpha-1-antitrypsin solution fraction obtained is stored as a liquid, frozen or freezedried preparation.

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18. (Currently Amended) A medicament containing an A1AT <u>alpha-1-antitrypsin</u> according to claim 12 as a sole active ingredient or in combination with anti-inflammatory agents[[,]] preferably steroids, NSAIDs.

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- 19. (Currently Amended) Use of the A1AT according to claim 12 for preparing a medicament for the treatment of A1AT deficiency, A method of treating a degenerative phenomena of the lung, such as lung fibrosis and emphysema the method comprising administering the alpha-1-antitrypsin of claim 12 to a subject in need thereof.
- 20. (New) The alpha-1-antitrypsin of claim 12, wherein the residual detergent content is < 10 ppm.